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**VIA CM/ECF**

Jarrett B. Perlow  
Clerk of the Court  
U.S. Court of Appeals for the Federal Circuit  
717 Madison Place, N.W.  
Washington, DC 20439

Re: *Salix Pharmaceuticals, Ltd. v. Norwich Pharmaceuticals Inc.*,  
Nos. 22-2153 & 23-1952

Dear Mr. Perlow:

Pursuant to Rule 28(j), Cross-Appellant writes in response to Appellants' submission regarding the Memorandum Opinion in *Norwich Pharmaceuticals, Inc. v. Becerra*. D.I. 61.

The D.C. district court found that the Delaware court's 271(e) order "unambiguously directed" that FDA not approve Norwich's Amended ANDA until the expiration of the HE Patents (Opinion at 38), even though the Amended ANDA has not been adjudicated to infringe the HE Patents under 35 U.S.C. § 271(e)(2)(A) and provides section viii statements – not Paragraph IV certifications – to the HE Patents. The Opinion thus accepts that the scope and injunctive force of the Delaware court's 271(e) order exceeds the infringement determination on which such orders must be premised. *See Prin. & Resp. Br.* at 15-18, 24-25. This mismatch is the basis for Norwich's cross-appeal to this Court.

While the correctness of the Delaware court's 271(e) order was not at issue before the D.C. district court, the Opinion acknowledges that Norwich has raised "a substantial argument" regarding FDA's regulation that permits ANDA filers to remove an indication that has been found to infringe and amend the Paragraph IV certifications to section viii statements for the infringed patents. Opinion at 34. *See Prin. & Resp. Br.* at 20-21; Reply Br. at 8-10.

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The D.C. district court’s discussion of *Ferring*, *Forest Laboratories*, and *Allergan*, and reference to some hypothetical “unfair[] prejudice [to] patent holders,” is in the context of the Delaware court’s Rule 60(b) order. Opinion at 35-37. It is also *dicta*, as the Opinion expresses “no view on the ultimate merits of these questions—and, certainly, takes no view on how these principles might apply to the Delaware District Court’s Rule 60(b) decision.” *Id.* at 37. Further, and consistent with Norwich’s argument to this Court (Prin. & Resp. Br. at 32; Reply Br. at 13-15, 23-24), the Opinion notes that “the relief that Norwich sought before the Delaware District Court is not on all fours with any of these cases.” Opinion at 37.

Respectfully submitted,

/s/ Chad A. Landmon  
*Counsel for Cross-Appellant*